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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,950	06/18/2001	Donald R. Ricci	13202.00267	6067

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT PAPER NUMBER

3763

DATE MAILED: 08/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,950

Applicant(s)

RICCI ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-120 is/are pending in the application.
- 4a) Of the above claim(s) 92-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-91, 116-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. This application contains claims 92-115 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 61, 64-69, 73,76-81, 85-86 , 116-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.5902331 to Bonner et al.

Bonner teaches a an endocardial cardiac lead comprising a catheter 80, a guidewire 56, 156; and an endovascular sleeve 10 comprising a first tubular passage 71 and a second tubular passageway 61 fixed with respect to one another the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second distal end, the first distal end extending beyond than the second distal end to define a junction with abuts against a crotch in the bifurcated body passageway; said guidewire being disposed in the first tubular passageway and the second tubular passageway is free of any guidewire. The first and second passages both have a substantially circular cross-section. The tubular

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passageways are each constructed of a material having sufficient integrity to be navigated though tortuous body passageways.

Bonner does not show the second tubular proximal end extending proximally from the patient. However as demonstrated in figure 5, the two tubular passageway are connected via an engaging means which is not permanently attached and hence the relationship between the two tubular passageways is capable of being modified to have the first tubular passageway extend distally beyond the distal end of the second tubular passageway.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the first tubular passageway extend distally beyond the distal end of the second tubular passageway because Applicant has not disclosed that the difference in position of the tubular passages provide an advantage, is used for particular purpose, or solves stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well because they both perform the same function.

Therefore it would have been an obvious matter of design choice to modify Bonner to obtain the invention as specified in claim 61.

3. Claims 62-63, 67-69, 74-75, 85-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.5902331 to Bonner et al, and further in view of US Patent No.566924 to Shaknovich.

As mentioned above Bonner teaches the claimed invention except for a radiopaque marker, a bifurcated stent, and two balloons. Shaknovich teaches a Y-shuttle stent assembly with a radiopaque marker, a bifurcated stent, and two balloons.

Therefore it would have been an obvious to one having ordinary skill in the art at the time the invention was made to have added Shaknovich's limitation to Bonner's apparatus. Because as with any type of catheter or sleeve introduced in to the body it would be a great advantage for the physician to locate the catheter/sleeve in the body via a radiopaque marker as indicated in Shaknovich. Furthermore to introduce a stent at a bifurcation there needs to be two balloons with stents placed on each to allow the stent to extend in the bifurcation. In order to achieve sufficient expansion of the stent along its entire length and to anchor the stent in the target vessel, the balloon used for employment is optimally, when inflated, there is a need for two balloon one for each stent.

4. Claims 70-72 and 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.5902331 to Bonner et al, and further in view of US Patent No.5830196 to Hicks.

As mentioned above Bonner teaches the claimed invention except for a first and second tubular passages having a chamfered shaped distal ends. Hicks teaches a tapered and reinforced catheter

Therefore it would have been an obvious to one having ordinary skill in the art at the time the invention was made to have added Hicks limitation to Bonner's apparatus,

because the tapered or chamfered shape at the tip of the sleeve or catheter minimizes insertion trauma in to the lumen. (Abstract)

Response to Arguments

5. Applicant's arguments with respect to claims 61 and 73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

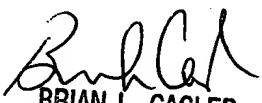
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG

August 25, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700